DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 11, 2013

Renovis Surgical Technologies, Incorporated
% Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept Incorporated
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K143647
Trade/Device Name: Renovis Surgical Hip Replacement System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: OQG, OQI, LPH, LZO
Dated: April 10, 2015
Received: April 13, 2015

Dear Dr. Orton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143647

Device Name
Renovis Surgical Hip Replacement System

Indications for Use *(Describe)*
Indications for Use:

The Renovis Surgical Hip Replacement System is indicated for patients suffering from:
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and
5. Revision procedures where other treatment or devices have failed.

The Renovis A400 Hip System is intended for cementless applications unless used with the Renovis Cemented Hip Stem.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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RENOVIS

Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K143647

A) Submitted by: Renovis Surgical Technologies
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Fax: 909-307-8571

Official Contact: Anthony DeBenedictis
Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721

B) Common name: Prosthesis, Hip Revision System

Proprietary Name: Renovis Surgical Hip Replacement System

Device Class: Class II

Regulations and Classification names: 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Product codes: OQI
LZO
OQG
LPH

Classification panel: Orthopedic

C) Predicates: K112897 Renovis A400 Surgical Hip Joint Replacement Prosthesis (femoral stems)

D) Date Prepared: April 29, 2015

E) Device Description:

The subject of this application are Renovis 4.5mm and 5.25mm femoral stems (and a 5.25 mm broach) which are an expansion of the FDA cleared Renovis A400 Surgical Hip Joint

Replacement Prosthesis (K112897) which is now known as the Renovis Surgical Hip Replacement System. The 4.5mm and 5.25mm femoral stems are the same material, the same configuration and will be offered in the same standard and lateralized offsets, as are the FDA cleared Renovis A400 femoral stems.

In addition, this application includes an update of Letter-to-File expansions and changes to the Renovis Surgical Hip Replacement System.

Renovis implants and instruments comply with the following material standards:

- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM A564-13 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes
- ASTM F1537-11 Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
- ASTM A276-13a Standard Specification for Stainless Steel Bars and Shapes
- ASTM A240-14 Standard Specification for Chromium and Chromium-Nickel Stainless Steel Plate, Sheet, and Strip for Pressure Vessels and for General Applications

E) Intended Use/Indications For Use:

The Renovis Surgical Hip Replacement System is indicated for patients suffering from:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and
5. Revision procedures where other treatment or devices have failed.

The Renovis A400 Hip System is intended for cementless applications unless used with the Renovis Cemented Hip Stem.

F) Substantial Equivalence Comparison and Discussion

The Renovis 4.5mm and 5.25mm femoral stems have the same Indications for Use, are manufactured from the same material, have the same configuration, will use the same offset options, and are provided sterile like the cleared Renovis A400 femoral stems. The difference is that they are offered in a smaller size and there is a change in the plasma spray manufacturing. The results of assessment and performance testing under design controls support that the 4.5 mm and 5.25 mm femoral stems do not raise new issues of safety and effectiveness.

G) Non-clinical Testing

The 4.5mm and 5.25mm femoral stems have been assessed for risk per Renovis SOP and were either accepted into previous static/fatigue testing, or successfully completed fatigue testing per the following standard:

- ISO 7206-4: 2010 Implants for surgery - Partial and total hip-joint prostheses - Part 4: Determination of endurance properties and performance of stemmed femoral components

Additionally, coating characterization of the 4.5mm and 5.25mm femoral stems was conducted.

There is no change in biocompatibility, sterilization, packaging or shelf life.

Conclusion

The Renovis 4.5mm and 5.25mm femoral stems are substantially equivalent to the FDA cleared Renovis A400 femoral stems, and are expected to perform per their Indications for Use as evidenced by assessment and/or bench testing under Design Controls.

H) Additional Consensus Standards and Guidance

- ASTM F565-04 (reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- ASTM F983-86 (reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components
- Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; guidance for Industry and FDA" dated April 30, 2002
- Non-clinical Information for Femoral Stem Prostheses" dated September 17, 2007.